REMARKS/ARGUMENTS

Claims 1-10, 14, 16-18, and 20-24 are currently pending in the present application. No amendments have been made to the claims with the filing of this response. Applicant wishes to thank the Office for withdrawing the previous objection to and rejection of the claims.

Reconsideration of the present claims is requested in view of the remarks below.

Rejection under 35 U.S.C. § 103(a)

The rejection of claims 1-10, 14, 16-18 and 20- 24 under 35 U.S.C. § 103(a) as obvious over Chaudary et al. (EP 019662) in view of Brown et al. (US 2002/0068791) is respectfully traversed.

Applying the inflexible rule promulgated by the Supreme Court and re-emphasized by the Federal Circuit, discussed *infra*, the claimed inventions are unobvious, since the Office has not provided a reason or any evidence that would have "led" or "prompted" one to modify the cited references to achieve the claimed invention.

In particular, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") recently ruled in chemical cases, such as *Takeda Chemical Industries, Ltd. v. Alphapharm Pty., Ltd.* 492 F.3d 1350 (Fed. Cir. 2007) ("*Takeda*")[1], although flexibility is required under the *Graham v. John Deere* (citations omitted) standard of determining obviousness, one inflexible rule is that a prima facie obviousness rejection requires at least "some reason" that would have led a chemist to modify the prior art in a particular manner.[2]

In *Takeda*, the Federal Circuit upheld a lower court's finding that the claims[3] of the patent-in-suit were not obvious. The court held, *inter alia*, that (1) a person of ordinary skill in the art would not have selected closest prior art compound; and (2) a person of ordinary skill in the art would not have been prompted to modify closest prior art compound, using certain

[1] Alphapharm filed an ANDA with the FDA to begin making a generic version of Takeda's patented diabetes treatment. The district court found the invention nonobvious, but Alphapharm requested that the Federal Circuit review the case under the standards of *KSR v. Teleflex*. On appeal, the Federal Circuit affirmed. *Takeda*, 492 F.3d at 1352.

[2] "[I]t remains necessary to identify some reason that would have led a chemist [to make the modification]." *Takeda*, 492 F.3d at 1357.

[3] The asserted claims in the patent-in-suit included claims 1 and 2, relating to compounds, and claim 5, relating to a composition containing the compounds. *Takeda*, 492 F.3d at 1353.

method steps, to synthesize the claimed compound. *Takeda*, 492 F.3d at 1350. The court indicated that "[w]e do not accept Alphapharm's assertion that *KSR International Co. v. Teleflex Inc.,* 127 S.Ct. 1727 (2007) ("*KSR*"), as well as another case recently decided by this court, *Pfizer, Inc. v. Apotex, Inc.,* 480 F.3d 1348 (Fed. Cir. 2007), mandates reversal."[4] In particular, the court found that "the closest prior art [described] properties that would have directed one of ordinary skill in the art away from that compound." *Takeda*, 492 F.3d at 1359.

Turning to the present case, regarding Chaudary et al., the reference generally describes a water-in-oil emulsion of a water-soluble polymer. This water-soluble polymer is a direct product of an inverse emulsion polymerization process. *See* abstract of Chaudary et al. According to Chaudary et al., the polymerization can be effected using a redox or thermal free radical initiators which may be oil- or water-soluble. *See* page 3, lines 11-13 of Chaudary et al.

Regarding Brown et al., the reference generally describes a process for preparing an aqueous emulsion polymer including providing at least one ethylenically unsaturated monomer and a free radical redox initiator system under emulsion polymerization conditions, in which the redox initiator system includes a water-soluble oxidizing agent, a water-insoluble oxidizing agent, and a sulfuric acid, or salts thereof reducing agent. *See* abstract of Brown et al. The reference also describes a process for reducing the residual ethylenically unsaturated monomer content of an aqueous emulsion polymer. *See id.*

As acknowledged by the Office, Chaudary et al. fails as a prior art reference for at least the following *several* differences between the reference and the claimed inventions:

a) The 2-hydroxy-2-sulflnato acetic acid, as a reducing agent of a redox initiator, in claim 1 is not described in Chaudary et al. (nor is there any indication that any known redox or thermal free radical initiators may be used);

b) The redox initiator and oil-in-water emulsifier, added to water-in-oil emulsion instead of aqueous monomer solutions, according to the present invention, particularly claims 4 and 20, is not described in Chaudary et al.;

c) The residual monomer content according to claim 7, speck content according to

[4] "Relying on *KSR,* Alphapharm [had argued] that the claimed compounds would have been obvious because the prior art compound fell within "the objective reach of the claim," and the evidence demonstrated that using the techniques of homologation and ring-walking would have been 'obvious to try.'" *Takeda*, 492 F.3d at 1359.

claim 9, and gel body content according to claim 14, are not described in Chaudary et al.;

d) The solid composition according to claim 10 is not described in Chaudary et al.; and

e) Chaudary et al. does not describe or indicate that a technical problem relating to induction times during polymerization should be avoided, as recited in claim 16.

See Present Office Action at pages 4-5.

However, the Office alleges that Brown et al. cures the above deficiencies/differences, and therefore the claimed invention is obvious in view of the references. Applicant disagrees with these allegations for the reasons indicated below.

Turning to the above difference a), one would not have been "led" or "prompted" to modify Chaudary et al. with Brown et al. in view of the following:

According to paragraph [0012] of Brown et al., the oxidant and reductant of the redox initiator system are typically added to the reaction mixture in separate streams, preferably concurrently with a monomer mixture. The monomer mixture may be added neat or an emulsion in water. The monomer mixture may also be added in one or more additions or continuously, linearly or not, over the reaction period, or combinations thereof.

In an emulsion polymerization, in accordance with the disclosure of Brown et al., the water-insoluble monomers are emulsified in water, and a redox initiator system, which comprises a water-soluble oxidizing agent, a water-insoluble oxidizing agent and a sulfinic acid or salts thereof as reducing agent, is used. As such, because Brown et al. describe a *conventional* emulsion polymerization reaction (well known in the art), see paragraph [0010], the polymerization reaction occurs in small drops of the at least one ethylenically unsaturated monomer, which are emulsified in the aqueous phase.

According to the Office, a person having ordinary skill in the art would have taken Brown et al. into account, in order to obtain the knowledge that 2-hydroxy-2-sulflnato acetic acid and/or a salt thereof is a very advantageous reducing agent of an initiator system, which should be used in an inverse emulsion polymerization reaction according to the present application.

However, Applicant points out that in an inverse emulsion polymerization reaction, water-soluble monomers are dissolved in an aqueous medium, and the aqueous medium is

emulsified in a hydrocarbon or a hydrophobic medium. Moreover, the monomers which have to be polymerized are dissolved in water droplets, which are emulsified in the hydrophobic medium, e.g., in a hydrocarbon.

Therefore, Chaudary et al. and Brown et al. describe completely different methods for preparing polymers, since Chaudary et al. describes a method, in which a water-soluble monomer is dissolved in water, and these water droplets are emulsified in a hydrocarbon, and Brown et al. describes a method for the preparation of a polymer, in which at least one ethylenically unsaturated monomer, which is not dissolved in any suitable solvent, is emulsified in water.

Applicant further points out that there is no description or suggestion in either reference that a reducing agent, which is advantageously used in a redox initiator system and in a conventional emulsion polymerization reaction, would be useful or advantageous in an inverse emulsion polymerization reaction. In particular, as one skilled in the art would know, the conditions and demands on the initiator system are completely different for an emulsion polymerization reaction compared to an inverse emulsion polymerization reaction.

Turning to the above difference b), one would not have been "led" or "prompted" to modify Chaudary et al. with Brown et al. in view of the following:

According to Chaudary et al., first an aqueous phase is prepared, comprising the monomers in water. Secondly, an oil phase is prepared, comprising emulsifier. These two phases are mixed, and a redox initiator, being a mixture of 0.2 parts ammoniumpersulphate in one part water and 0.1 parts sodiummethabissulfite in 5 parts water are added. *See* Example 1 of Chaudary et al.

In contrast to this disclosure, according to the present application, first an oil phase is prepared, in which at least one water-in-oil-emulsifier or at least one protective colloid is dissolved in hydrophobic liquid inert for the polymerization. Secondly, the monomers, an oil-in-water-emulsifier and at least one redox initiator are dissolved in an aqueous phase. These two phases are mixed and homopolymerization or copolymerization of the monomers used, and optionally further co-monomers, is conducted. *See* claims 1 and 4 and the present specification at page 10, lines 11-22.

A difference between the two ways of addition of the components of the polymerization reaction is that according to the present invention, the redox initiator system is far better distributed in the whole reaction mixture, compared to Chaudary et al. In particular, according to Chaudary et al., the redox initiator system is added to the emulsion of the aqueous and the oil phase. In contrast, according to the present application, the initiator system is well dissolved or dispersed in the aqueous phase, and subsequently, the two phases are mixed and polymerization reaction is started. *See* claims 1 and 4 of the present invention.

As such, the disclosure of Chaudary et al., i.e., that the initiator system shall be added to the complete emulsion ready for polymerization, does not describe or indicate that the initiator system shall be well dissolved or dispersed in the aqueous phase prior to mixing the oil and the aqueous phases. Further, based on the differences concerning the disclosure of Brown et al., discussed *supra*, there is clearly nothing in the reference that would have lead one to modify the initiator system in Chaudary et al. to achieve the claimed invention.

Turning to the above difference c), one would not have been "led" or "prompted" to modify Chaudary et al. with Brown et al. in view of the following:

According to the present specification at page 3, lines 23-30, 2-hydroxy-2-sulfinato acetic acid and/or a salt thereof as reducing agent helps that the homopolymerization or copolymerization takes place according to the process of the invention without an induction period. As a result, the desired advantageous product properties, in particular good speck and gel body contents, of the polymers and W/O emulsions prepared by this process are achieved.

As a result, the residual monomer content of claim 7, the speck content of claim 9 and gel body content of claim 14 are based on the specific use of 2-hydroxy-sulfinato acetic acid as die reducing agent of an initiator system. Since the disclosure of Chaudary et al. does not point in the direction of this reducing agent and its advantageous use compared to other reducing agents for redox initiator systems, a residual monomer content, spec content and gel body content according to the present application is clearly not suggested by Chaudary et al.

Regarding Brown et al., discussed *supra*, the reference describes a completely different way of preparing polymers. Therefore, although Brown et al. uses 2-hydroxy-2-sulfinato acetic acid, this disclosure clearly would not have prompted or led one in the direction of the process

according to the present application, resulting in polymers or polymer emulsions having the specific residual monomer content, speck content and gel body content.

Turning to the above difference d), one would not have been "led" or "prompted" to modify Chaudary et al. with Brown et al. in view of the following:

In claim 10 of the present application, a solid composition is claimed, comprising at least one water-in-oil emulsifier or at least one protective colloid, at least one oil-in-water emulsifier (wetting agent) and at least one homopolymer or copolymer according to the claimed invention (claim 6), and optionally customary additives. However, based on the process for the preparation of homopolymers or copolymers according to the present application, discussed *supra*, these polymers are obtained having advantageous characteristic features that are not described or suggested by Chaudary et al. and/or Brown et al. *See also* page 3, lines 23-30 and page 10, lines 5-10 of the present specification. Moreover, as discussed *supra*, the Office has not provided any reason or evidence, other than hindsight of the present specification, that would formulate a homopolymer or copolymer having the resulting features of the present invention, based on the disclosures of these references.

Turning to cited difference e) above, one would not have been "led" or "prompted" to modify Chaudary et al. with Brown et al. in view of the following:

The induction time of the process for the polymerization according to claim 16 of the present application can be shortened by the use of 2-hydroxy-2-sultlnato acetic acid and/or a salt thereof as reducing component. Applicant notes that the above point and a further advantage, in which more reactive polymer chains can be started in a very short time, were discussed and shown in the Amendment filed June 1, 2007, pages 6-12.

Moreover, Applicant points out that even though, *arguendo*, Brown et al. describes the use of 2-hydroxy-2-sulfinato acetic acid as a reducing agent in an initiator system which can be used in a conventional emulsion polymerization reaction, discussed *supra*, this disclosure would still not lead one in the direction of the process according to claim 16 of the present application. In particular, one of ordinary skill in the art, considering a method for *inverse emulsion* polymerization reaction, clearly would not consider or rely on the disclosure of Brown et al. for

reducing agents, since the techniques and results obtained are different.

In view of the above reasons, the claimed inventions are not obvious over Chaudary et al. and/or Brown et al. Therefore, the rejection is improper. Accordingly, withdrawal of the rejection is kindly requested.

Applicant believes the pending application is in condition for allowance. Early notification of the same is kindly requested.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 03-2775, under Order No. 13156-00037-US from which the undersigned is authorized to draw.

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Respectfully submitted,

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